

CERTIFICATE OF ANALYSIS

(Certificate No. KMO001008-01)

Release Date: 22/02/2024

Re-test Date: 21/02/2027

Omeprazole OME VIII

Identification

Chemical Name :

8-methoxy-1,3-dimethyl-12-thioxobenzo[4',5']imidazo[2',1':2,3]imidazo[1,5-a]pyridin-2(12H)-one

Alt. Name

: Omeprazole BP Impurity F , Isomer of
Omeprazole EP Impurity G ,
Omeprazole USP Related Compound F

CAT No.

: KMO001008

CAS No.

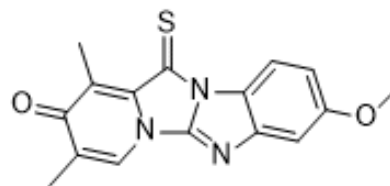
: 125656-82-8

Molecular Formula

: C₁₆H₁₃N₃O₂S

Molecular Weight

: 311.36



Analytical Information

Batch No.

: OME-RCF-073-088

Solubility

: THF

Description

: Brown Solid

Mass

: Confirm

HPLC Purity

: 92.94 %

IR

: Confirm

Weight Loss By TGA

: 1.59 %

¹H NMR

: Confirm

% Potency

: 91.46 %

Additional Information

Long Term Storage

: Store at 2-8 deg. C for long term storage

Shipping Condition

: Product is stable to be shipped at room temperature

% Potency = [100 - 1.59(Weight Loss By TGA)] x [92.94(HPLC Purity)]/100 = 91.46 %

Recommendation

: Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		22/02/2024
Reviewed & Approved By	Quality Control	Jatin Patel		22/02/2024

Attachments : COA, HPLC, MASS, ¹HNMR, IR and TGA